

US EPA ARCHIVE DOCUMENT

I. Introduction

A. Background

On August 2nd, 1999 the US Environmental Protection Agency, Office of Pesticide Programs issued in the Federal Register (64FR42943) a Notice of Availability (along with a request for comment) for the draft PR Notice entitled, "Worker Risk Mitigation for Organophosphate Pesticides." This document announces EPA's approach for managing risk to workers who may be exposed to organophosphate (OP) pesticide products. This approach generally provides for basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or personal protective equipment, as well as increased restricted-entry intervals, for occupational situations where these measures are feasible and where current risk assessments indicate that they are necessary.

A total of eight comments were received on the draft PR Notice (submitted under docket # OPP-34191). Comments were received from the California Department of Pesticide Regulation, National Agricultural Aviation Association (NAAA), Pest Management Regulatory Agency of Health Canada (PMRA), Farmworker Justice Fund, ServiceMaster (Terminix International), Columbia Legal Services, and the Alliance for Reasonable Regulation of Insecticides (ARRI).

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B. Organization of this Document

This document contains OPP's responses to the comments raised on the draft PR Notice. Due to the length and diversity of individual comments received, this document is organized in sections by commenter, and each section contains a brief synopsis of the comments, and the Agency's response. The complete text of the comments can be found in the OPP public docket.

Some of the responses include discussion of the comments received on specific questions posed by OPP in the Notice of Availability. The specific questions posed in the draft PR Notice were:

- Is EPA's definition of closed systems and closed cabs too broad or too specific? Should EPA adopt the same standards as California for closed systems?
- What technologies are available or under development to reduce exposure to occupational users in green houses and during orchard

applications? Are there other agricultural applications for which closed cabs are not currently feasible?

- The Pesticide Registration Notice gives one example of the industry moving toward automated or technological replacements for human occupational users (the substitution of Geographic Positioning Systems (GPS) or mechanical flaggers for human flaggers in aerial applications). Are there other examples where agricultural work functions could be automated?
- In many cases, existing re-entry intervals (REIs) for organophosphate pesticide uses may be inadequate. Where feasible, EPA will seek to extend re-entry intervals, however, there are practical limits on the length of re-entry intervals. What other measures should EPA consider to protect occupational users re-entering treated fields? Is testing/monitoring of plant residues prior to harvest practical?
- For retained uses where exposure to occupational users is still a concern, EPA may require biological monitoring for occupational user populations of concern. As many organophosphate pesticide uses are of concern, what is the most efficient approach to monitoring occupational user populations?

II. Response to Comments

- A. California Department of Pesticide Regulation (CADPR)
- B. National Agricultural Aviation Association (NAAA)
- C. Pest Management Regulatory Agency of Health Canada (PMRA)
- D. Farmworker Justice Fund
- E. ServiceMaster - Terminix International (pest control company)
- F. Alliance for Reasonable Regulation of Insecticides (ARRI)
- G. Columbia Legal Services (provides representation to low income people, including migrant and seasonal farm workers in Washington State)

A. California Department of Pesticide Regulation (CADPR)

Comment: Clarify what is meant by closed systems and enclosed cabs. Mention the closed system and enclosed cab standard being developed by American Society of Agricultural Engineers (ASAE) in the final PR. In addition, clarify the difference between a closed system and a mechanical transfer system

Response: The Agency is aware that ASAE has developed standards for enclosed cabs and may require enclosed cabs that meet the ASAE standard on a case-by-case basis depending on the risk. The ASAE standard for closed systems is still in development, and the Agency will consider it when it is complete.

A mechanical transfer system is designed by the manufacturer to transfer liquid pesticide in a manner that prevents the liquid, but not necessarily any vapor, from *contacting handlers or other people during the transfer. Since this system does not protect against inhalation exposures, it would generally not qualify as a closed system*

for chemicals with inhalation exposure concerns; however, it is considered an engineering control which greatly reduces dermal exposure. The PR Notice has been revised to reflect these clarifications.

Comment: The Draft PR Notice does not permit qualitative or quantitative comparison with the policies currently in place at DPR for mitigation of occupational exposure to pesticides.

Response: The purpose of the Worker PR Notice is to serve as general guidance to manufacturers, producers, formulators and registrants. The Agency will continue to work with California DPR and other stakeholders in formulating individual pesticide decisions. Pesticide specific comparisons of risk assessments and risk management decisions are the best way to conduct qualitative and quantitative comparisons.

Comment: Like the WPS, the proposed approach appears to be an interim measure to mitigate risk. The notice does not indicate that the mitigation measures will become mandatory.

Response: Although the Agency encourages registrants to demonstrate stewardship of their chemicals by adopting protective measures prior to the issuance of the interim RED, specific measures for individual chemicals will be mandated in a given time frame through EPA's interim Reregistration Decision documents. In addition, the PR Notice was intended to allow producers and users more time to adjust to the possible regulatory requirements by providing advance notification. The PR Notice has been revised to emphasize that worker risk mitigation is not voluntary.

Comment: If risks are not adequately mitigated by the WPS, the Agency should implement revisions evenly and with a compliance date.

Response: The Agency is reviewing each chemical on a case-by-case basis, and intends to implement mitigation in a fair, consistent, and timely manner. As noted above, the interim REDs will include a compliance date.

B. National Agricultural Aviation Association (NAAA)

Comment: Advances have been made in the aviation industry which are not taken into account through Pesticide Handler's Exposure Data (PHED). EPA should require registrants to submit new studies that would incorporate the changes in methodology. NAAA is willing to assist in the conduct of the studies. New or updated technologies that aren't sufficiently accounted for in PHED are automated flaggers, the common use of GPS, closed cockpits, nozzle technology and boom-lowering systems.

Response: The Agency acknowledges that some data in PHED have shortcomings, and encourages groups such as NAAA to submit data that could be used to further refine worker risk assessments. It is, however, likely that although new technologies have been developed there is still a wide range in the technologies that are actually used, and

much of this range is likely reflected in the PHED data. The Agency is working with NAAA to better characterize how representative PHED data are compared to current practices.

Comment: EPA should be flexible to reassess occupational exposure as new technologies are developed (e.g. electrostatic spray charging technology).

Response: *In addition to developing exposure data, registrants would need to specifically require the use of these new technologies on pesticide product labels in order for EPA to reassess risks. Without labels clearly limiting the application methods, the Agency must assume, for example, that human flaggers are used. The Agency acknowledges the information submitted on electrostatic spray; however, exposure data conforming to EPA guidelines would be needed to assess the actual exposure reduction resulting from the use of that technology.*

C. **Pest Management Regulatory Agency of Health Canada (PMRA)**

Canada's comments are a direct response to the questions asked by the Agency (listed at the beginning of this document).

Comment: Evaluation of the feasibility of proposed risk mitigation measures and the ability to monitor for compliance should be part of the decision-making process.

Response: EPA agrees that feasibility of mitigation and compliance are important risk management considerations. Prior to finalizing a risk management decision, the Agency typically participates in several conference calls with USDA, growers, registrants and others to assess the feasibility of proposed mitigation measures. EPA's Office of Enforcement and Compliance Assistance (OECA) and state lead agencies who are responsible for monitoring for compliance with required mitigation measures are also included in the decision making process.

Comment: The definition of a closed system is too broad. CA has a more detailed and clear definition, which is preferable.

Response: The purpose of the Worker PR Notice was not to limit the definition of closed systems, but to give examples of types of engineering controls that may be used to mitigate worker risk and to encourage innovative technologies to reduce exposure to workers. The Worker PR Notice has been modified to include more descriptive examples of engineering controls that may be required in risk management decisions. In addition, the Agency has recently funded a study through Cornell University to catalog the different closed systems that are currently available, including information on the following: closed transfer systems, returnable/refillable containers, carbon cab filters, chemical induction bowls, diaphragm check valves, hydraulic boom folding, nozzles/holders, injection devices, and tank rinsing devices. This study is currently targeted for completion in late 2001. In the risk assessment and risk management processes, the amount of exposure reduction that is actually provided by the proposed system is taken into consideration. In general, the Agency will be more prescriptive in requiring which closed system to use depending on the level of concern for risk.

Comment: Does the Agency regulate the integrity of products packaged in water soluble bags, for example with tests under humidity, various temperatures, and drop tests?

Response: The Agency does not regulate the integrity of product packaging; however, the Department of Transportation (DOT) does do some testing of packaging integrity. DOT tests may include drop tests, leakproofness tests, hydrostatic pressure tests, stacking, and cooperage tests. Depending on the design of the bag, it may be retested once every 12 or 24 months. For more information on testing of packaging integrity, readers are referred to the [DOT's Office of Hazardous Materials Safety](#).

Comment: Canada does not consider water soluble packaging a closed system due to potential splashing when mixing and loading to applicator vehicle.

Response: Under the WPS, water soluble bags are considered to be a closed system until they lose their integrity in the mix tank. EPA considers water soluble packaging to be a protective engineering control during pesticide loading.

Comment: The definition of closed systems in the Worker PR Notice for mixing and loading does not encompass granules which are not diluted prior to application.

Response: Some technologies are available for granular formulations, where the granules are packaged into a container that fastens directly onto specially made application equipment. Once attached, the equipment opens the container and meters out the granules. Under the WPS, such systems meet the definition of closed loading system and closed application system and reduced PPE is permitted.

Comment: For greenhouses uses, chemigation, overhead irrigation, or drip irrigation may reduce exposure. Stationary foggers, delayed activation mechanisms, or remote control activation devices may also reduce exposure. In orchards use of different types of spray technologies may reduce exposure (electrostatic sprayers, computer controlled airblast sprayers). Seed treatments and seed planting can be automated.

Response: These technologies will be evaluated on a case-by-case basis. Again, exposure data are needed to quantify the protection afforded by such technologies. However, when the risk warrants extra protective measures, these types of technologies may be required along with data to quantify exposure reduction.

Comment: When considering REIs, personal comfort plays a factor in determining the level of PPE actually worn. For many cultivation practices, the level of clothing and protective equipment is related to the activity; e.g. gloves are often worn to prevent mechanical abrasion and irritation from plant material. In addition, suits made of protective material such as Tyvek® could be required to be distributed at the point of sale of the product. Depending on feasibility, the Agency should consider different REI's for different post-application activities.

Response: EPA acknowledges that workers sometimes use gloves or other items to protect them from abrasion or irritation. While these may somewhat reduce exposures to pesticide residues, it cannot be assumed that these practices are carried out

consistently and are done across the board. EPA typically does not require PPE for reentry workers to protect them from pesticide residues due to evidence that it is impractical, and the concern that heat-stress may actually increase the risk of injury. In addition, some practices (gloves in particular) may increase risk of pesticide exposure if they are not maintained properly. The Agency has found that hired agricultural workers, especially harvesters, have a disincentive to wear PPE; because they frequently are paid at a piece rate, and they have little tolerance for anything that hinders their speed and efficiency. While "different REIs" for the same crop/chemical are not permitted under WPS, the Agency currently considers exceptions to the REIs, where the potential level of exposure may be less for certain time-critical reentry activities and where data are available regarding the duration and extent of these various activities.

Comment: Consider requiring on-site surveillance of workers to watch for symptoms of over exposure.

Response: On-site surveillance of workers is beyond the scope of the Worker PR Notice; however, WPS does require pesticide handler monitoring for certain high risk uses (labels with skull and crossbones, and greenhouse fumigants). On-site surveillance may be considered on a case-by-case basis.

D. Farmworker Justice Fund

Comment: When the Agency's mitigation measures (engineering controls and REIs) are not sufficient to protect workers' health, the Agency must seek cancellation of uses, not propose inadequate mitigation measures. There is no incentive for a registrant to produce a safer product or voluntarily accept significant restrictions on the use of its product if the Agency does not seek cancellations when safety standards are exceeded. The Agency must seek cancellation of uses if engineering controls and extended REI's don't provide an adequate margin of safety and alternative pest management methods are available. When the risk is high and alternative products exist, the Agency should initiate suspension of the pesticide, rather than seek "voluntary" use of inadequate engineering controls as an interim measure.

Response: The Agency will seek cancellation of uses if available risk mitigation measures, such as engineering controls and extended REI's, do not provide an adequate margin of safety and the risks outweigh the benefits.

The management of risks identified in the OP assessments is governed by two standards. The "reasonable certainty of no harm" standard in section 408 of the FFDCA, applies to the establishment and reassessment of tolerances, governs all food uses, and generally does not allow consideration of benefits. The "no unreasonable adverse effects on the environment" standard of FIFRA includes consideration of occupational and ecological risks, as well as the economic, social, and environmental costs and benefits of the pesticide's use.

The Agency may consider cancellation of some use sites, application methods and products or chemicals when mitigation measures are not sufficient to protect the health and safety of workers. However, in the case of worker risks, FIFRA mandates a risk/benefit analysis before seeking cancellation. Therefore, EPA assesses potential benefits before making a risk management decision.

Comment: By allowing continued use of dangerous pesticides such as azinphos methyl or methyl parathion, the Agency is sending the message that farmworkers are second class citizens whose safety can be sacrificed

Response: EPA takes the health and safety of all workers very seriously. Ultimately, decisions made by the Agency must be in accordance with the statutes which govern pesticide regulation, which require risk/benefit considerations in the case of worker risk. The Agency has not made determinations of risk management for worker or ecological risk for these chemicals yet; the mitigation measures that were required for methyl parathion and azinphos methyl were put in place to reduce overall exposure until the time of the interim REDs.

In the case of azinphos-methyl, EPA required enclosed cabs or full PPE (PPE must be chemical resistant and include a respirator), additional PPE, increased REIs, required data on closed mixing and loading systems, prohibited hand held applications, prohibited chemigation, restricted use on ornamentals to use on nursery stock, dropped use sites, reduced application rates and number of applications per season, required immediate label amendments, and required implementation of the Worker PR Notice.

In the case of methyl parathion, EPA required reduced application rates and fewer applications per season on some crops, deleted use on many fruit and vegetable crops, deleted all ornamental uses, prohibited hand held applications, increased REIs, and required immediate label changes. EPA has required additional dislodgeable foliar residue data as well as biomonitoring data on existing mixing and loading systems; based on these data, closed cab systems may be required.

Comment: The PR notice relies on voluntary measures and mitigation where feasible. It is unlikely that such measures will be found to be "feasible" or will be voluntarily adopted.

Response: The Agency is encouraging registrants to add protective measures to their labels now on a voluntary basis, however, EPA will require label changes when the interim RED is issued. The PR Notice has been revised to clarify this point (Many risk mitigation measures result from negotiations with the registrant which result in voluntary agreements. The Agency has found that this is often the quickest way to achieve the desired outcomes. Although the agreements are voluntary, the fulfillment of the agreements are viewed by the Agency as a mandatory requirement.)

Comment: MOEs of 100 or more should still require engineering controls instead of PPE. Engineering controls are more protective, but also preferable because of the widespread noncompliance with PPE requirements.

Response: EPA would generally not pursue mitigation beyond what is necessary to achieve an adequate margin of safety. In some instances, requiring engineering controls would make more sense than additional PPE. For example, if heat stress were a concern, EPA would work with registrants and stakeholders to move to engineering controls rather than more PPE. In order to require engineering controls, the Agency must consider viability and feasibility of such requirements. The Agency promotes engineering controls as more protective when viable for a given work situation; however there are some scenarios in which engineering controls are not possible.

Comment: Other classes of pesticides also need additional safety measures, not just OPs.

Response: EPA agrees - the Worker PR Notice focuses on organophosphates because those are the chemicals that are currently at the front of the reregistration process. However as other classes of pesticides go through reregistration, EPA envisions that pesticides with similar risks, e.g., carbamate pesticides, could be managed in a similar manner. In addition, EPA has required engineering controls and other worker protection measures in the past for many other chemicals through the registration and reregistration processes.

Comment: Enclosed cabs must be equipped with charcoal filters or respirators, and have air conditioning. Applicators will open the windows of cabs that don't have air conditioning, thus defeating the purpose of the enclosed cab.

Response: By definition in the Worker Protection Standard for Agricultural Pesticides, an enclosed cab must have a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside the cab. If applicators open the windows of cabs for any reason, they are no longer using an enclosed cab. During the development of the WPS, EPA carefully considered whether to require all enclosed cabs to be equipped with organic-vapor-absorbing filters and air conditioning. However, the Agency concluded that for many pesticides and in many pesticide-use situations, an enclosed cab that provides dermal protection alone is sufficiently protective. For example, many pesticides do not pose an inhalation concern when applied by motorized ground equipment and no respirator is required for applicators using open cabs. In this situation, it would be unnecessary to require an enclosed cab to filter air with expensive, relatively short-lived organic-vapor-absorbing filters. Only pesticides that are highly to moderately toxic by route of inhalation and have relatively high vapor pressure trigger the use of a vapor-absorbing respirator. In most situations where a respirator is required for applicators using motorized ground equipment, a dust/mist respirator is sufficient. Therefore, the Agency determined that requiring all enclosed cabs to be equipped with organic-vapor-removing filtration systems was unnecessary, particularly in view of the high cost for such equipment.

With respect to air conditioning, EPA agrees that using an enclosed cab in hot weather without an air conditioner would be uncomfortably hot. However, there are many pesticide-use situations where the weather is not hot. In the spring and fall in some areas, ground equipment operators use heaters, rather than air conditioners. The

Agency determined that it was unwarranted to require all enclosed cabs to be equipped with air conditioners. EPA believes that prudent applicators will purchase or retrofit their ground equipment with enclosed cabs appropriate for the weather conditions where they work and for the pesticides they apply. In rare instances, when merited by the severity of the inhalation risks to ground equipment applicators, EPA may specify through pesticide labeling requirements that enclosed cabs meet certain inhalation-protection performance criteria, such as the ASAE standard for enclosed cabs.

The Agency notes that under the WPS, for most pesticides, when a respirator is required for ground equipment applicators, applicators are given a choice whether to use an enclosed cab that provides equivalent respiratory protection to the type of respirator being required or to wear the appropriate respirator while inside the enclosed cab. EPA concluded that this option offered the most flexibility for applicators, while still providing adequate safety protection.

Comment: Aerial applications of toxicity category I and II products, as well as likely carcinogens, teratogens, reproductive toxicants, and other neurotoxins should be prohibited to protect workers in neighboring fields and worker's families. Workers affected by drift should be afforded a right to know the pesticide to which they have been exposed and be given immediate transportation to an emergency medical facility.

Response: This comment is beyond the scope of the Worker PR Notice. However, the Agency is in the process of developing a drift policy and a methodology for assessing risks to workers and others resulting from chemical drift. Readers are referred to: Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B- Postapplication Exposure Monitoring Test Guidelines, the Draft: Standard Operating Procedures for Residential Exposure Assessment, and the Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment presented at the September 1999 meeting of the FIFRA Scientific Advisory Panel. These policies are currently being revised and should be available soon. The Agency will be expanding the scope of the residential exposure assessments by developing guidance for characterizing exposures from sources currently not addressed such as spray drift; residential residue track-in; exposures to farmworker children; and exposures to children in schools. EPA would not generally prohibit a given application method based on toxicity characteristics alone. Risk assessments rely on consideration of both toxicity and exposure.

The WPS requires that agricultural workers be notified in a central location of the product name, EPA registration number, active ingredient, the location, time and date of application, and REI of pesticide applications. In addition, the central location should include emergency information and a pesticide safety poster. In the case of emergency, employees covered by WPS must be provided emergency transportation to a medical facility. The employer may either take the employee to a medical facility, call an emergency vehicle such as an ambulance, or make sure the employee has a ride with someone else. In the case of workers who are not covered by WPS, specific notification

and emergency transportation requirements may be required on specific chemical labels.

Comment: The Agency continues to rely on PPE, which increases the risk of heat-related illnesses to workers. PPE is inadequate (noncompliance). If a pesticide can't be made safe with engineering controls, it should be removed from the market.

Response: PPE is more appropriate than engineering controls for some uses, and in some cases, engineering controls are not available. When engineering controls are not available and risks cannot be adequately reduced with PPE or changes in use patterns, EPA will weigh the benefits and risks as required by FIFRA before making a regulatory decision.

Comment: All workers should be given access to showers and laundry facilities on the agricultural establishment where they work.

Response: Again, this comment is beyond the scope of the Worker PR Notice, however the WPS has decontamination requirements for both workers and pesticide handlers to perform routine washing after work, and for emergency washing in case of an accident. Also, employers are required by WPS to clean and maintain workers' PPE.

Comment: The PR Notice should contain a clear statement of the Agency's intention to prohibit greenhouse or orchard use of OPs where necessary engineering controls are found to be infeasible.

Response: EPA will seek ways to adequately reduce risks in all situations where engineering controls are not feasible. If risk reduction measures are not available and risks outweigh the benefits, EPA will consider cancellation. The purpose of the PR Notice is to provide the public and the regulated community with general guidance on the Agency's approach to managing risks to workers - not to categorically prohibit specific uses. Such decisions will be made based on the individual OP risk assessments.

Comment: The PR Notice should also state the Agency's intention to prohibit the use of backpack sprayers or the like with toxicity category I and II OPs and other chemicals.

Response: This is considered on a case-by-case basis in risk assessments taking into account both acute and longer term effects, exposure and toxicity of each chemical. It is possible for some pesticides that exposures from certain application methods such as hand-held equipment (backpack sprayers, handwands and knapsacks), can not be mitigated adequately by PPE or other measures. In situations where these application methods are not mitigated adequately by PPE or other measures, and risks exceed benefits, the Agency will consider cancellation of the use.

Comment: Mandated application rates and number of applications is an illusory protection without enforcement and stiff penalties. Users should be required to provide an enforcement agency a notice with specific dates on which pesticides were applied.

Response: The pesticide regulation system is based on the label and is enforced by states. By mandating certain application rates and numbers of applications, the Agency

helps to ensure that the least amount of pesticide that is efficacious is used. FIFRA prohibits the EPA from collecting data from endusers. However, the Farm Bill authorizes USDA to collect usage data, and individual states may also require reporting.

Comment: The PR Notice does not protect rural residents (farmworkers and children) who are frequently in the fields or live adjacent to fields. The fetuses of pregnant farmworkers are not protected, and there are no calculated REIs for 40 lb children who may be in the field.

Response: This comment is beyond the scope of the Worker PR Notice. Again, the Agency is in the process of developing a drift policy and a methodology for assessing risks to workers and others resulting from chemical drift. In assessing risk to farmworkers and children, the Agency relies predominantly on data developed using test animals to make judgments about potential effects on humans. These include acute toxic reactions, such as poisoning and skin and eye irritation, as well as long-term effects like cancer, birth defects and reproductive system disorders. Several of the types of studies that are considered are designed specifically to assess risks to infants and children. The Agency assesses toxicity information with data about physical and chemical properties of the pesticide, information on how the pesticide will be applied, and other exposure information to estimate potential risk. Where appropriate, the Agency routinely adds one or more uncertainty factors to ensure an adequate margin of safety. If the Agency determines that it is not possible to assess risk accurately with available data, the Agency will require the pesticide registrant to develop additional data. The Hazard Identification Assessment Review Committee addresses concerns for protecting fetuses in the review of developmental toxicants; this is reflected in the endpoint selection. The Agency is currently developing a policy paper to address risks posed to children and how risk assessments consider hired children (age 12 and above).

EPA's current reentry risk assessments do not calculate exposures to 40 lb children. However, the Agency agrees that it is important to address risk to farm worker children whether by pesticide-regulation or by other means.

Readers are referred to a report released by the General Accounting Office (GAO) entitled "Pesticides: Improvement Needed to Ensure the Safety of Farmworkers and Their Children" PDF (GAO/RCED-00-40), which includes a statement from the Agency on the ongoing activities within the Agency to protect children from exposure on a field or drift from a treated field. "The Agency agrees that it is important to fully assess whether farmworker children are currently at risk and to address that risk. In a generic sense, the Agency, particularly since promulgation of FQPA, has been examining the special vulnerabilities of children, as well as how to estimate exposure to children from typical activities. We have put our findings into use in support of regulatory decisions, such as tolerance reassessment, that are protective of all children. Specific to farmchildren, EPA is also examining whether some of the activities it has already investigated, like playing on a treated lawn, are analogous to exposures farm children may receive."

EPA is concerned about the possible disproportionate exposure of farm children to pesticides and has several ongoing projects designed to both assess and reduce these exposures. Some of EPA's major efforts in this area are described below:

EPA's major external research program, Science to Achieve Results (STAR) program allocated funds in fiscal year 1996 for three years of research on the most urgent issues regarding exposure of children to pesticides. The studies are looking at major types of exposure (touching, eating, crawling, etc.) and at seasonal and locational differences, including agricultural settings. This research will support regulations and public education efforts that are more fully protective of children, for example through revised use restrictions and labeling requirements, and improved training and public information materials. Under the STAR program, the University of Arizona is assessing exposure of the children of seasonal and migrant laborers to agricultural pesticides. In addition, the University of Washington is assessing, on a comprehensive seasonal basis, children's exposures to organophosphate pesticides.

EPA's National Center for Environmental Research and Quality Assurance of the Office of Research and Development is funding a grant with the University of California at Berkeley for a five-year study, that began in August 1998, to quantify the exposure of children in agricultural areas of California to pesticides. The project will integrate biological research with community-based intervention efforts. The study will determine the impacts of pesticide exposure on children's growth and development. The University will also work with the farm worker community to investigate approaches for reducing these exposures.

Based on recommendations from the Children's Health Protection Advisory Committee (CHPAC), EPA has committed to conduct a national assessment of implementation and enforcement of the Worker Protection Standard, including its effectiveness in addressing the safety needs of women and children as agricultural workers.

Comment: The PR Notice does not protect exposure from contaminated clothing.

Response: The Worker PR Notice was not intended to address this particular issue. The Agency refers the reader to the both the WPS and the label, which does address exposure from contaminated clothing. For example, training required under the WPS includes information about washing work clothing separately from other laundry before re-use. Many labels instruct workers to discard clothing that has been contaminated.

Comment: PR Notices are not an adequate vehicle for regulating worker safety.

Response: The PR notice is not intended to serve as regulation, it is a notice and provides general guidance to the registrants and the public on how the agency intends to manage risks from organophosphate pesticides. Worker safety is regulated by certification and training, worker protection rules and by label requirements. Risk mitigation for individual OPs will be implemented through interim REDs.

E. ServiceMaster - Terminix International (pest control company)

Comment: Inhalation exposure to workers from use of hand-held equipment is negligible due to the dilution of the a.i., and the equipment used (the commenter referenced a study, "Measurement of Pesticides in Air During Application to Lawns, Trees and Shrubs in Urban Environments").

Response: Available data indicate that inhalation toxicity and exposure vary among chemicals, even among OPs. The Agency uses actual inhalation data when available and surrogate data when necessary to estimate inhalation risk. Any available data concerning inhalation exposure should be submitted to the Agency for review.

Comment: Additional garment layers increases risk of heat exhaustion, and are not an acceptable risk reduction measure.

Response: The Agency agrees that additional layers may increase the risk of heat exhaustion, however it is a viable risk reduction measure for many use scenarios.

Comment: The Agency should not require PPE that is exorbitant in cost, or impossible to obtain (example of \$175 viton gloves 14 mil. - not in production)

Response: Typically, EPA provides several options rather than one specific type of equipment. PPE is selected for pesticides on a case-by-case basis, after careful consideration of potential risks, level of protection provided, and cost relative to additional protection.

Comment: Biological Monitoring should be used as a risk reduction measure where exposures from using certain application equipment, such as hand-held equipment, cannot be adequately mitigated by PPE.

Response: The Agency recognizes that some industries routinely monitor employees cholinesterase levels. This type of information is of limited use to the Agency unless it can be tied to specific application and exposure scenarios.

Comment: Overlapping jurisdiction of protection of handlers and applicators at the state level is problematic; the EPA-OSHA memorandum of understanding is either unknown to or not acknowledged by OSHA personnel.

Response: This comment is beyond the scope of the PR Notice. The Agency notes this comment and agrees that there is some overlap between the two agencies. Any apparent contradictions with OSHA will be addressed on a case-by-case basis.

F. Alliance for Reasonable Regulation of Insecticides (ARRI)

Comment: Critical science policies should be finalized and occupational risk assessments updated accordingly (i.e. Human Testing and Toxicity Endpoint Selection for ChE Inhibiting Pesticides). ARRI asserts that targeting a risk mitigation policy proposal at the organophosphate class of chemicals is premature, because the Agency has finalized neither the majority of occupational risk assessments for organophosphate chemicals, nor the science policies on which these risk assessments are to be based. EPA's own risk

assessment guidance clearly stipulates that risk management steps are to be taken following completion of the risk characterization step.

Response: EPA is committed to the principles outlined by Vice President Gore to have an open and transparent process, a reasonable transition to alternative products, and the use of sound science. It is primarily for that reason that the TRAC was formed and the pilot process for increased public participation in pesticide decisions was developed. However, EPA must balance the goal of providing for greater transparency and participation in development of science policy with its mission to ensure the safety of the food supply and the health of consumers, especially children, workers, and the environment. In order to accomplish our mission through timely decision making, EPA has established an ambitious schedule for completion of individual OP risk assessments and development of risk mitigation options. It should also be noted that FFDCA does establish a statutory deadline to complete the reassessment of existing tolerances by 2006, and the Agency is making every effort to comply with that deadline.

The Agency is in the process of finalizing its policy on Toxicity Endpoint Selection. A draft policy was made available for public comment in Nov. of 1999, and has been extensively rewritten to reflect input from both internal and external sources. A response to comments will be issued along with the final policy paper.

On July 27, 1998, Administrator Carol Browner committed the Agency to make no final decisions under FFDCA based on human studies until a policy was in place to ensure that such studies meet the highest scientific and ethical standards. This interim policy has been repeated in numerous public forums, and discussed with the TRAC committee. In December of 1998 and November of 1999, a joint Science Advisory Board and [Science Advisory Panel](#) (SAB/SAP) held a meeting, which was open to the public, to discuss issues related to data derived from testing on human subjects and its use in pesticides risk assessments. The report that will come out of the SAB/SAP meeting will form the basis of a policy paper that will be available for public comment.

Comment: The Agency can do more to train and educate.

Response: The Agency is currently undertaking a review of the certification and training and worker protection programs. The Certification and Training Advisory Group (CTAG) issued recommendations last summer to improve the applicator certification program. The national assessment of the WPS has begun and the first major meeting will be held in June. Major topics will be enforcement, worker training and education, including right to know information requirements and restricted entry intervals. It is expected that the WPS assessment will result in recommendations to improve the training and education of farm workers.

Comment: Recognize industry initiatives (i.e. Best Management Practices (BMP) Task Force - white papers attached); develop incentives for other new projects aimed at worker safety.

Response: The Agency frequently works with Industry to give guidance and recognition to special projects (for example the Agricultural Reentry Task Force).

Comment: The BMP found that the three major areas which could be addressed for risk mitigation initiatives by the Task Force were equipment, formulation and education.

Response: The Agency agrees and encourages advances in worker protection such as formulation changes, new equipment, education and better training of workers.

Comment: Discuss formulation and equipment technology in more depth in the PR Notice.

Response: The formulation and equipment technology section of the PR Notice has been expanded, however the Worker PR Notice is intended as guidance and is not meant to be a detailed reference on those topics. EPA has contacted Cornell to develop a "catalog" of technology options. EPA does not want to limit innovation by providing specific or rigid guidelines for technology.

Comment: Expand on risk vs. benefits section of PR notice. When and how are risk benefits considered in an risk management decisions? How are benefits information collected?

Response: Benefits are examined on a case-by-case basis, depending on the level of risk and the mitigation options available. Benefit information is most often considered after all feasible mitigation measures have been considered, and risks are still of concern. Benefits information that is considered includes a variety of use-related information, such as how each pesticide is applied, where and when it is used, how much is actually used, what it controls, and what alternative controls are available. Use-related data cover the extent of pesticide use across different sites and geographic regions, typical use patterns, use profiles for specific pesticides, and the role of pesticides in pest management systems. The availability, efficacy, cost, and risks associated with alternative pest controls are also important considerations when benefits information is considered.

Comment: There is no scientific basis at this time for generalizing about the chemical class in any way that pertains to worker risk. Focusing on organophosphates is fundamentally arbitrary and unfair. Focus instead on hazard and exposure information for specific chemicals.

Response: EPA has now completed the majority of the worker risk assessments for the OPs and has found that they do pose a common type of risk to workers. In making risk management decisions, the Agency focuses on hazard and exposure information for specific chemicals. As noted previously, the OPs as a class are the focus of this PR notice because they are now undergoing reregistration and tolerance reassessment and, in general, both individually and collectively pose worker risks of concern.

Comment: The voluntary nature of the PR Notice does not provide any concrete incentives. In addition, the statement that the Agency will consider canceling uses if risks exceed benefits is in contradiction to the "voluntary" nature of the PR Notice.

Response: The PR Notice is general guidance, and does not preclude the risk/benefit part of FIFRA. The EPA encourages registrants to demonstrate good stewardship of their products by voluntarily adopting measures to reduce risks to the maximum extent possible; however, risk mitigation will be required at the time of the interim RED.

Comment: Avoid drastic actions - foster a spirit of cooperation rather than threat of cancellation.

Response: One purpose of the Worker PR Notice is to give some advance notice to the regulated community on EPA's approach to managing worker risks. In addition, the Agency has involved interested parties in the regulatory process for the OPs via public meetings and comment periods established by the TRAC. The PR Notice does not intend to threaten cancellation, but only to lay out the risk management process, which in some specific situations may involve cancellation.

G. Columbia Legal Services (provides representation to low income people, including migrant and seasonal farm workers in Washington State

Comment: Due to under reporting problems, current incident data represents only the "tip of the iceberg" in terms of the scope of health risks posed by these pesticides.

Response: The Agency agrees that cases of pesticide poisoning incidents among the agricultural work force are likely to be significantly more numerous than those that are reported. For further information on this topic, readers are referred to the "Regulatory Impact Analysis of Worker Protection Standard for Agricultural Pesticides," August 11, 1992.

Comment: The Agency must consider the routine noncompliance with existing PPE requirements in assessing the effectiveness of additional requirements to mitigate worker exposure (gave an example of 9 of 10 inspections had WPS violations).

Response: The risk assessments do not factor in noncompliance because the label is the legal way to use a pesticide. If the Agency found high noncompliance we would consider other options. Again, EPA's Office of Enforcement and Compliance Assurance and state lead agencies do monitor for compliance.

Comment: Children in particular are at risk and are not sufficiently protected. Farm worker children are likely to be exposed simultaneously to several pesticides that are not registered for household use and that have the same mechanism of toxicity.

Response: See the response above in the comments from the Farmworker Justice Fund regarding farm worker children and family exposure.

Comment: If there is an insufficient margin of safety for worker exposure, and alternatives are available, the use must be canceled under FIFRA. If no alternative exists

the Agency must assess real world compliance with, and maintenance of, engineering controls and PPE in determining whether these measures are sufficient to protect workers from OP exposure. Uses with an insufficient MOE should be canceled. Where logistical constraints make adequate protection infeasible, the use should be canceled (i.e. greenhouses, and orchards). Where exposures from methods such as hand held equipment cannot be mitigated by PPE or other measures, those methods must be prohibited. When risk exceeds benefit and no alternatives are available the use should be canceled. "Consideration" of cancellation is inadequate.

Response: FIFRA is a risk/benefit standard; when there is an insufficient margin of safety for worker exposure, the benefits of the pesticide are analyzed, and the Agency may consider cancellation. Again, the PR Notice provides only general guidance and lays out what will be considered. If the risk are determined to outweigh the benefits, and all feasible mitigation has been exhausted, cancellation is a likely outcome.

Comment: Human flaggers should be prohibited where alternatives are available.

Response: The Agency agrees that mechanical flagging or GPS is preferable to human flaggers, and encourages label restrictions that would prohibit human flaggers when risk assessments indicate a need for mitigation. In addition, the Worker PR Notice encourages registrants to amend labels to require use of alternative measures to human flaggers.

Comment: The Agency should require chemical-specific training on pesticides to which workers will be exposed, including the REI for each pesticide. REIs must be enforceable.

Response: In the Worker Protection Standard the Agency requires general safety training, and information about REIs and interpreting other chemical-specific safety requirements. Pesticide labels provide information on hazards, precautions, first aid, symptoms of poisoning and PPE required for early entry into treated fields. Also, please refer to the response above on the ARRI comment regarding training and certification.

Comment: The Agency should move forward with the reregistration process for OPs and must not rely on the possibility of voluntary risk reduction measures as suggested by the PR Notice.

Response: EPA will impose risk reduction measures through the interim RED decisions. The PR Notice is intended as general guidance, and is not the vehicle by which the chemicals will be regulated. The PR Notice has been clarified to state that risk mitigation is not voluntary. Only early implementation is voluntary.

Comment: If the Agency determines that risk mitigation is necessary prior to final action on a pesticide, it should impose emergency risk reduction measures up to and including suspension of the use under FIFRA.

Response: Depending on the severity of the risk associated with the specific chemical, the Agency may require immediate risk reduction measures.

Comment: The Agency should similarly protect farm workers from other neurotoxins, probable carcinogens and teratagens.

Response: FQPA requires EPA to assess chemicals posing the greatest risk first. In developing its schedule for tolerance reassessment (see 62 FR 42019) EPA has grouped all pesticides subject to reassessment into three groups. Group 1 includes not only OPs, but also carbamates and probable & possible carcinogens. See the comment/response in the ARRI and Farmworker Justice Fund sections for a response on this topic.